REMARKS

Claims 1-69 are pending in the present application with claims 16-35, 42-58, and 69 withdrawn from consideration. Claims 1-6, 8, 9, 36, 37, and 59-65, 67, and 68 stand rejected in the Office Action dated October 21, 2010.

Applicants would like to thank the Examiner for giving careful consideration to Applicants' previously submitted remarks. Applicants would also like to thank the Examiner for indicating that claims 7, 10-15, 38-41, and 66 would be allowable if rewritten to include all of the limitations of the base claims. However, Applicants submit that the presently cited art is deficient for the reasons stated below, and Applicants submit that claims 1 and 36, from which claims 10-15 and 38-41 depend either directly or indirectly, are allowable in view of the following remarks.

Claim Rejections – 35 U.S.C. §102(e)

Claims 1-6- 8, 9, 36, 37, 59-65, 67, and 68 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 7,367,935 (hereinafter "Mechlenburg").

The claims are directed to a system for providing transcranial magnetic stimulation (TMS) treatment to a patient. As previously amended, a TMS coil comprises a sensor that detects ***contact*** between the TMS coil and the patient, such that the output of the sensor is processed to indicate whether the TMS coil is properly disposed with respect to the ***position at which pulses are applied during application of pulses to said TMS coil***.

Mechlenburg describes a device for stimulating muscles in the airway of the neck for the relief of a breathing disorder. The device may include a collar and sensors on the collar, such as a temperature sensor, that may detect when the appliance is disposed on the patient. The office action asserts that these sensors correspond to the claimed sensors. Applicants respectfully disagree with the assertion for the following reasons.

Mechlenburg describes sensors on a collar that indicate when a collar is disposed on a patient (Mechlenberg, col. 17, lines 55-60). Mechlenburg does not, however, provide an indication whether a treatment coil is properly disposed on the patient with respect to any

particular position based on the sensor output. Rather, for proper positioning, Mechlenburg relies on the use of arrows on the collar that the user aligns with the chin along the centerline of the face or another physical feature of the patient, such as the carotid artery (Mechlenberg, col. 13, lines 1-16). The sensors, on the other hand, are merely used for power conservation and the coil is simply either activated or deactivated based on the temperature sensor. For example, Mechlenberg's sensors merely indicate whether a collar is disposed on the neck of the patient, and if the collar is not disposed on the neck, power is conserved by automatically turning off the device. The sensors described in Mechlenburg may detect a temperature, but they do not detect contact between a transcranial magnetic stimulation coil used for treatment and a position at which pulses are applied. In contrast to the claimed embodiments, Mechlenberg's sensors do not aid an operator in the proper positioning of the treatment device.

Further, nowhere does Mechlenburg teach or suggest that the temperature sensors are disposed between the TMS coil and a position at which pulses are applied. The office action refers to the description of Mechlenberg's sensor 62, suggesting that sensor 62 is disposed between the TMS coil and a position at which pulses are applied. However, sensor 62 also does not detect contact between a transcranial magnetic stimulation coil used for treatment and a position at which pulses are applied. Rather, sensor 62 is used to "prevent electrical energy from being provided to coil 56 in the event that heat generated by energizing the coil exceeds a predetermined threshold." The output of sensor 62 does not provide any indication of whether the TMS coil is properly disposed with respect to any particular position during application of pulses to said TMS coil.

Further, Mechlenberg's sensor 62 is preferably not located between the coil and a position at which pulses are to be applied. Figure 3 depicts both the sensor 62 and the coil 56. The targeted areas for stimulation in Mechlenburg are the sternothryoid 46, sternohyoid 42, and thyrohoid 44 muscles, such that "the area of increased magnetic field strength created…is targeted toward the sternothryoid 46, sternohyoid 42, and thyrohoid 44 muscles." However, Mechlenburg states that it is desirable to locate sensor 62 in an area where the magnetic field intensity is at a minimum; in other words, ***not*** near the targeted treatment area or a position at

which pulses are to be applied. Mechlenberg's sensors are therefore preferably not located between the coil and a position at which pulses are to be applied.

Thus, Mechlenburg does not teach a ***transcranial*** magnetic stimulation (TMS) system that indicates whether the TMS coil is properly disposed ***with respect to the position at which pulses are applied during application of pulses***. In particular, Mechlenburg does not teach a sensor disposed between the ***TMS coil*** and ***a position at which pulses are applied*** detects contact between the TMS coil and the patient, where the output of the sensor can be used to indicate whether the TMS coil is properly disposed ***with respect to the position at which pulses are applied during application of pulses***.

Accordingly, Applicants respectfully submit that independent claims 1, 36, and 59 and the claims that depend therefrom patentably define over the cited references and are in condition for allowance. Applicants request withdrawal of the rejection of claims 1-9, 36-41, and 59-68 under 35 U.S.C. §102 or §103. Reconsideration of the office action and a Notice of Allowance are respectfully requested.

Claim Rejections – 35 U.S.C. §103(a)

Claims 36 ,37

Independent Claim 36 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pub. No. 2001/0002441 ("Boveja"). Claim 37, which depends from claim 36, stands rejected under 35 U.S.C. §103(a) as being unpatentable over Boveja in view of U.S. Pub. No. 2004/0167592 ("Grove").

Claim 36 recites a device that detects the proximity of a TMS coil to a position of a patient during TMS patient, where a sensor is disposed on a flexible substrate.

The Office Action asserts that the only difference between the device described in Boveja and that recited in the claims is that Boveja does not disclose a sensor disposed in a flexible substrate. However, there are many differences between Boveja's device with the claimed device.

First, nowhere does Boveja teach or suggest the use of a coil for treatment of a patient using a magnetic field, much less for the recited treatment involving transcranial magnetic stimulation. Rather, Boveja sets forth the use of external and implantable coils as ***proximity*** sensing components, not ***treatment*** components (Boveja, paras. [0052]-[0053]). In particular, Boveja describes properly aligning external coil circuitry with implanted coil circuitry based on the direction and strength of a field applied from a magnet contained in the implanted coil to the external coil. Proper location of the coils is determined based on desired parameters of the field measured from the magnet to the sensors. Thus, Boveja's coils are used for ***placement*** of the circuitry containing the coils, not for the ***treatment*** of the patient as recited in the claims.

Further, Boveja's sensor does not detect contact between the TMS coil and the patient. Rather, Boveja's sensor merely indicate location based on parameters of the field measured from a magnet contained in the implanted coil.

In addition, Boveja's method of neuromodulation therapy used to treat urinary incontinence and urological disorders is accomplished via ***electrical*** stimulation, not by using a magnetic field as recited in the claims. Boveja describes neuromodulation therapy that uses a lead receiver implanted subcutaneously, and electrodes at the end of the receiver are positioned in a sacral nerve. Treatment is accomplished by ***electrically*** stimulating the electrodes at the end of the implanted receiver via an external stimulator, thus ***electrically*** stimulating the sacral nerve (Boveja, paras. [0050]-[0051]). Thus, Boveja's treatment is accomplished through ***electrical*** stimulation and does not teach the use of "a ***transcranial magnetic stimulation*** coil for treating a patient using a ***magnetic*** field." As described above, the magnetic field aspect described in Boveja is used for ***placement***, not ***treatment***.

Furthermore, Boveja does not teach a sensor that is disposed ***between*** a TMS coil and a position at which pulses are applied. Boveja's sensing components are ***contained in*** the coils and used at a distance apart (one implanted, one external) (Boveja, [0052]-[0053], *also see* sensor component 50 in FIGs. 7, 8). Thus, Boveja does not teach a sensor that is "disposed ***between*** the coil and a position at which pulses are applied."

Accordingly, Applicants respectfully submit that claim 36 and claim 37, that depends from claim 36, patentably define over the cited reference. Applicants request withdrawal of the rejection of claims 36 and 37 under 35 U.S.C. 103(a) and withdrawal of the objection to allowable claims 38-41.

Conclusion

In the event that the Examiner cannot allow the present application for any reason, the Examiner is encouraged to contact the undersigned attorney, Lori Swanson at (215) 564-8997 to discuss the resolution of any remaining issues.

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